

Attorney Docket No. 20784/4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Demuth et al.

09/745,776 Art U

Art Unit: 1614

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FILED:

U.S.S.N.:

12/22/2000

Examiner: Not yet assigned

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FOR:

PRODRUGS OF DP IV INHIBITORS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on April 2001.

By:

Michelle M. Guinazzo

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FIRST ACTION ON THE MERITS)

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Date April 2,2001

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner. Copies of the listed items are enclosed.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

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I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)
 - a. Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
 - b. A concise explanation of the relevance of all patents, publications or other information listed that are not in the English language are as follows:

FRENCH LANGUAGE FR 2 696 740 apparently relates to Dimethylbiguanide drug derivatives and their medical applications.

FRENCH LANGUAGE FR 2 085 655 apparently relates to biguanide substitutes possessing a hypoglycemic property.

GERMAN LANGUAGE DT 25 42598 A1 apparently relates to biguanide salts as well as a method for preparing such salts. In addition to this the invention apparently covers pharmaceutical compounds which contain such salts.

GERMAN LANGUAGE WO97/40832 apparently relates to the use of a method for reducing in the blood of a mammal by administration of effectors the enzyme activity of dipeptidyl peptidase (DP IV) or enzyme activity similar to DP IV, the endogenous (or additionally exogenously administered) insulinotropic peptide gastric inhibitory polypeptide 1-42 and glucagon-like peptide amide-1 7-36 are decomposed in a causal sequence to a reduced extent by DP IV enzymes or those similar to DP IV.

JAPANESE PATENT JP 4334357A2: ACYL DERIVATIVE HAVING ENZYME-INHIBITING ACTION, apparently relates to a compound having a prolyl endopeptibase activity-inhibiting action and useful as an antidement agent, especially an anti-amnestic agent. **GERMAN PATENT DD296075A5**: VERFAHREN ZUR HERSTELLUNG NEUER INHIBITOREN DER DIPEPTIDYL PEPTIDASE IV, apparently relates to the preparation of preparing new inhibitors of dipeptidyl peptidase IV by synthesizing an aminoacid amide of formula A-B (I) from XAY or XA(Z)Y and B utilizing conventional peptide chemistry methods for forming amide bonds (See Derwent Abstract). c. [The following additional information is provided for the Examiner's consideration: **FEES** IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b) (check one box) a. | | within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required. ъ. within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required. c. 🖂 before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e)below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p). V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c): (check one box) before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)). a. No certification; therefore, a check in the amount of \$180.00 is enclosed as required by 37 C.F.R. . § 1.17(p).

or

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IDS USSN: 09/745,776 Page 4 See the certification below. No fee is required. VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e) (check only one box) The undersigned hereby certifies that each item of information contained in the IDS was cited in a a. | | communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or no item of information contained in the IDS was cited in a b. | communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement. c. | Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement. Please charge deposit account 50-0369 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached. 冈 No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge the appropriate any additional fees to Deposit Account No. 50-0369.

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The claims of the application as now presented are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application are respectfully requested.

Date: April 2, 2001

Respectfully submitted,

John C. Serio, Reg. No. 39,023 Brown Rudnick Freed & Gesmer

One Rinancial Center Boston, MA 02111 Tel: (617) 856-8238